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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,162	09/22/2003	Ronald R. Breaker	24519.6.8402	4368

53449 7590 01/27/2010

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EXAMINER	
ZARA, JANE J	
ART UNIT	**PAPER NUMBER**
1635	

NOTIFICATION DATE	DELIVERY MODE
01/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

agg.patent.docketing@agg.com

Office Action Summary	Application No.	Applicant(s)	
	10/669,162	BREAKER ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11-11-09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,20,21 and 46-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,20,21,46-58 and 70-91* is/are rejected.

7)☒ Claim(s) *59-69* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office action is in response to the communication filed 11-11-09.

Claims 1-7, 20, 21, 46-91 are pending in the instant application.

Response to Arguments and Amendments

Applicant's arguments with respect to claims 1-7, 20, 21, 46-58, 70-83 have been considered but are moot in view of the new ground(s) of rejection set forth below.

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 20, 21, 46-58, 70-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nahvi et al (Chem. & Biology, Vol. 9, pages 1043-1049, published online 9-19-2002) and Werstuck et al (Science, Vol. 282, pages 296-298, 1998), the combination in view of Gold et al (USPN 5,475,096).

The claims are drawn to regulatable gene expression constructs comprising a riboswitch which is derived from either a naturally occurring or conservative base sequences thereof, or from a non-naturally occurring riboswitch, and is operably linked to a coding region which is optionally an expression construct or recombinant polypeptide, which riboswitch comprises an aptamer domain and an expression platform domain, which aptamer domain comprises a P1 stem, which P1 stem comprises an aptamer strand and a heterologous control strand, and the expression platform comprises regulatory element which is optionally a transcription initiation site and comprises a regulated strand, and which regulated or control strand forms a stem structure, and which riboswitch is not derived from an adenosylcobalamin-responsive riboswitch, but is optionally derived from a FMN-repoonsive riboswitch or a guanine-responsive riboswitch, and wherein the sequence does not encode β-galactosidase.

Nahvi et al (Chem. & Biology, Vol. 9, pages 1043-1049, published online 9-19-2002) teach a gene expression construct comprising a riboswitch which is derived from either a naturally occurring or conservative base sequences thereof, or from a non-naturally occurring riboswitch, and is operably linked to a coding region which is

optionally an expression construct or recombinant polypeptide, which riboswitch comprises an aptamer domain and an expression platform domain, which aptamer domain comprises a P1 stem, which P1 stem comprises an aptamer strand and a heterologous control strand, and the expression platform comprises regulatory element which is optionally a transcription initiation site and comprises a regulated strand, and which regulated or control strand forms a stem structure, and which riboswitch is derived from an adenosylcobalamin-responsive riboswitch (see entire document, esp. figure 1 on p. 1044, figure 1 on p. 1045, figure 4 on p. 1046, figure 5 on p. 1047 and text on pages 1047-8).

Werstuck et al (Science, Vol. 282, pages 296-298, 1998) teach regulatable gene expression constructs comprising a nucleic acid molecule encoding an RNA comprising a riboswitch operably linked to a sequence encoding a protein , wherein the riboswitch regulates expression of the protein, wherein the riboswitch regulates transcription or translation of the sequence, which riboswitch comprises an aptamer domain and an expression platform domain, which riboswitch is optionally derived from a natural or a non-natural derivative, and which aptamer domain and expression platform domain are heterologous (See entire document, esp. Fig. 1 and 3).

The primary references do not teach riboswitches that are not derived from an adenosylcobalamin-responsive riboswitch, nor do they collectively teach sequences not encoding β-galactosidase.

Gold et al (USPN 5,475,096) teach methods to design, screen and optimize aptamers which bind to a predetermined ligand, including guanine and other non-adenosylcobalamin molecules (see entire text, esp. paragraph 48).

It would have been obvious to generate riboswitches comprising an aptamer domain targeted to non- adenosylcobalamin molecules because the ability to generate and screen for aptamers to a predetermined target ligand, including guanine, was well known in the art as taught previously by Gold et al. One would have been motivated to generate riboswitches targeting other ligands as a way of generating riboswitch molecules to use to measure a variety of ligands in a biological solution. One would have reasoanably expected that an array of aptamers generated using the routine experimentation well known in the art, and taught by Gold, would provide for the instantly claimed bioswitches, because Westruck and Nahvi teach the general methodology to design and synthesize riboswitches and omitting the β-galactoside portion of the detector molecule would have been a design choice. One would have reasonably expected that the riboswitches originally taught by Westruck and Nahvi could be modified to incorporate other aptamers recognizing a diverse set of target ligands, relying on the prior art teachings of Gold. One would also have reasonably expected that the riboswitches generated using these combined teachings would provide for molecules exhibiting dynamic interplay between the aptamer domain and expression platform domain because such dynamic allosterism was previously taught by both Westruck and Nahvi, and switching sequences within the riboswitches, and

swapping aptamers would have involved routine screening techniques and routine design choice using routine experimentation.

For these reasons, the instant invention would have been obvious to one of skill in the art at the time of filing.

Allowable Subject Matter

Claims 59-69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tracy Vivlemore, can be reached on (571) 272-2914. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
1-15-10

/Jane Zara/

Primary Examiner, Art Unit 1635